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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,484	11/28/2001	Yen Choo	8325-2004 G8-US1	2713
20855 7590 12/14/2007 ROBINS & PASTERNAK 1731 EMBARCADERO ROAD SUITE 230 PALO ALTO, CA 94303			EXAMINER SULLIVAN, DANIEL M	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 12/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/996,484	Applicant(s) CHOO ET AL.	
	Examiner Daniel M. Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7,8,10,11,13-15,21-26,31,34,35 and 38-48 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,5,7,8,10,11,13-15,21-26,31,35 and 38-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper 17 September 2007. Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 35 and 38-47 have been withdrawn from consideration and claims 34 and 48 were considered in the Final Office Action mailed 30 October 2006. Claims 1, 34, and 48 were amended in the 17 September Paper. Claims 1, 2, 4, 5, 7, 8, 10, 11, 13-15, 21-26, 31, 34, 35 and 38-48 are pending and claims 34 and 48 are under consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 17 September 2007 has been entered.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 103

Rejection of claim 48 under 35 U.S.C. 103(a) as being unpatentable over Vegeto *et al.* WO 93/23431 as evidenced by McEwan *et al.* (*supra*) and Bledsoe *et al.* (*supra*) in view of Liu *et al.* (1997) *Proc. Natl. Acad. Sci. USA* 94:5525-5530 is **withdrawn** in view of the amendment of the claims to require that the binding of the first polypeptide to the second polypeptide forms a heterodimer and the binding of the first and second polypeptides is mediated by binding of a

Art Unit: 1636

ligand to the first and second polypeptides. The cited art does not teach a first and second polypeptide that form a heterodimer or binding of a ligand to both the first and second polypeptides.

Claim Rejections - 35 USC § 102

Rejection of claim 34 under 35 U.S.C. 102(b) as being anticipated by Barbas et al. (1995) WO 95/19431 is **withdrawn** in view of the amendment of the claim to require a ligand that binds to the first and second polypeptides and mediates heterodimerization of the first and second polypeptides. Barbas et al. does not teach ligand mediated heterodimerization involving binding of the ligand to the first and second polypeptides.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilman et al. WO 96/06110.

Claim 34 is directed to a complex comprising a heterodimer comprising a first and second polypeptide, wherein the first and second polypeptides bind to DNA and the first or second polypeptide comprises an engineered Cys2-His2 zinc finger binding domain, and a ligand

Art Unit: 1636

that binds to the first and second polypeptides and mediates heterodimerization of the first and second polypeptides.

Claim 48 is directed to a switching system comprising a first and second polypeptide and a ligand in which the first polypeptide binds to the second polypeptide to form a heterodimer and the binding of the first and second polypeptides is mediated by binding the ligand to the first and second polypeptides, wherein the first and second polypeptides bind to DNA and the first or second polypeptide comprises an engineered Cys2-His2 zinc finger DNA binding domain.

Gilman et al. teaches composite DNA-binding proteins in which two or more heterologous DNA-binding domains are linked together through an association mediated by a multimerizing agent. (See, e.g., page 2, lines 9-13; page 3, lines 1-6; and page 8, lines 9-19.) Gilman et al. teaches that the multimerizer-linked composite DNA-binding proteins comprise two or more chimeric proteins, each comprising at least one binding site for a multimerizing ligand and at least one component DNA-binding domain. (See especially the first full paragraph on page 5.) Thus, Gilman et al. teaches a complex or switching system comprising first and second proteins and a ligand (i.e., multimerizing agent), wherein the ligand binds to both the first and second polypeptides such that the first and second polypeptides are joined to form a heterodimer (i.e., the polypeptides comprise, at least, heterologous DNA binding domains).

Finally, Gilman et al. teaches Cys2-His2 zinc finger DNA binding domains as one of a small number of explicitly named classes of DNA binding domains that might be comprised by the composite DNA-binding proteins. The Cys2-His2 zinc finger DNA-binding domains explicitly disclosed by Gilman et al. (see especially the zinc finger constructs described at pages 24-25) read on an engineered Cys2-His2 zinc finger binding domain insofar as there is no

Art Unit: 1636

limiting definition of “engineered” provided in the disclosure that would exclude zinc finger DNA binding domains produced by a process of natural selection from the scope of an “engineered” Cys2-His2 zinc finger binding domain. In addition, Gilman et al. teaches that the zinc finger DNA-binding domains can be engineered by mutagenesis to provide a DNA-binding domain having decreased, increased or altered recognition specificity of DNA binding. (See especially the first full paragraph on page 10.)

Gilman et al. teaches complex or switching system comprising each of the elements of the complex or switching system presently claimed—i.e., a heterodimer comprising a first and second polypeptide, wherein the first and second polypeptides bind to DNA and the first or second polypeptide comprises an engineered Cys2-His2 zinc finger binding domain, and a ligand that binds to the first and second polypeptides and mediates heterodimerization of the first and second polypeptides. Therefore, the claims are anticipated by Gilman et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC)

Art Unit: 1636

for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Daniel M. Sullivan/

Primary Examiner

Art Unit 1636